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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,952	08/17/2000	Michael S. Kinch	3220-66872	3252

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EXAMINER

DAVIS, NATALIE A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/02/2002 ( )

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/640,952

Applicant(s)

KINCH ET AL.

Examiner

Natalie A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13, 21-24 and 28-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 5-13, 21-24 is/are allowed.
- 6) ☒ Claim(s) 4 and 28-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicant's amendment filed 5 October 2001 (Paper No: 10) is acknowledged. Accordingly, claims 14-20, 25-27, and 82-89 are cancelled, and claims 1-13, 21-24, and 28-81 are pending.

2. Applicant's traversal of the election of Group I, claims 1-13, 21-24, and 28-71 is acknowledged. The traversal is on the ground(s) that the inventions of Groups I and IV may be searched without undue burden, as both groups are in the same class and subclass and interrelated so that a search of one group will reveal art to the other. This is not found persuasive for reasons set forth in the previous office action. Even though the methods of Groups I and IV are both drawn to methods of detecting metastatic cells, the methods of detection differ in mode of action. Group I detects the presence of metastatic cells by detecting EphA2 epitope, while Group IV assays for EphA2 localization patterns and phosphorylation content.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-13, 21-24, and 28-71 are being examined as belonging to the elected Group I, while claims 72-81 are withdrawn from examination as being drawn to a non-elected invention

### ***Information Disclosure Statement***

3. The information disclosure statement filed 11 October 2001 has been considered. A signed copy is attached hereto.

### ***Response to Arguments***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 103 Withdrawn***

5. Rejection of claims 1-8, 10-13, 21-24, and 28-71 over Pasquale, et al., Zantek, et al., and Kinch, et al, (paragrah 10) under 35 U.S.C. 103(a) is withdrawn in view of arguments.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 28-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the presence of metastatic cells, does not reasonably provide enablement for detecting potentially metastatic cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

8. Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The instant disclosure fails to meet the enablement requirement for the following reasons:

9. The nature invention is detection of potentially metastatic cells. The specification discloses methods of detecting the presence of metastasis using EphA2-specific antibodies, but does not provide any guidance or exemplification for the detection of potentially metastatic cells.

10. Pasquale, et al. is cited in order to establish the general state of the art of detecting potentially metastatic cells at the time the invention was made. Pasquale, et al. teach a method of diagnosing cancer and determining cancer prognosis wherein, the level Eph-related protein tyrosine kinase in a sample as compared to a normal sample is indicative of the presence of a cancer or the level of malignancy of a cancer and methods of determining Eph-related kinases using RNA and protein blot analysis, ELISA, using specific antibodies to the Eph-related kinase (col. 9). There is no evidence in the art teaching the detection potentially metastatic cells. Furthermore, the specification does not teach or exemplify how to recognize a potentially metastatic cell. One of ordinary skill in the art would not know how to recognize if a cell has the potential to become metastatic because the specification does not give any guidance as how to

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select for one. Accordingly, it would be unpredictable and would require undue experimentation to one skilled in the art to practice the claimed invention as the art and specification only teaches the detection of metastatic cells and not potentially metastatic cells.

11. The specification is objected to and claims 4, 31, 50, and 54 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from a written description (e.g. sequenced); or (3) deposited.

It unclear if a cell line which produces an antibody having the exact structural and chemical identity is known and publicly available, or can be reproducibly isolated without undue experimentation. Therefore, a suitable deposit for patent purposes is suggested. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of: (1) the claimed cell line; (2) a cell line which produces the chemically and functionally distinct antibody claimed; and/or (3) the claimed antibody's amino acid or nucleic acid sequence is an unpredictable event and it would require undue experimentation to reproduce the claimed antibody species. Deposit of the cell line producing the specified antibody would satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See, 37 C.F.R. 1.801-1.809.

The instant application does not provide the appropriate evidence of satisfying the deposit of the cell line producing D7 and B2D6 antibodies for the enforceable life of the patent.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications. Applicant's provision of these assurances would obviate this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, Ph.D.

December 20, 2001



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